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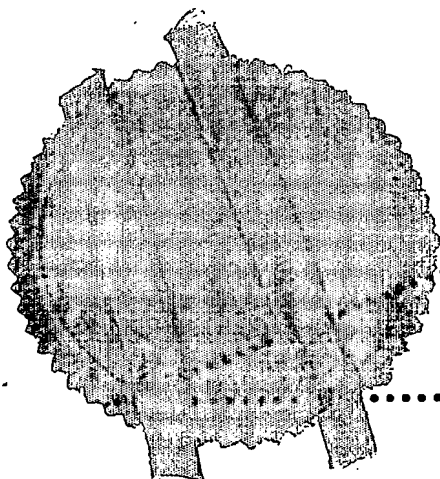
सत्यमेव जयते

Government Of India  
Patent Office  
Todi Estates, 3<sup>rd</sup> Floor,  
Lower Parel (West)  
Mumbai - 400 013

**THE PATENTS ACT, 1970**

IT IS HEREBY CERTIFIED THAT, the annex is a true copy  
of Application and Provisional Specification filed on 09/07/2003 in respect of Patent  
Application No.700/MUM/2003 of Cipla Limited, a company incorporated under the Indian  
Companies Act, 1913, of 289, Bellasis Road, Mumbai Central, Mumbai - 400 008, Maharashtra,  
India.

This certificate is issued under the powers vested in me under Section  
147(1) of the Patents Act, 1970.



.....  
Dated this 1<sup>st</sup> day of Sept 2004.

*(Signature)*  
(R. BHATTACHARYA)

CONTROLLER OF PATENTS & DESIGNS

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FORM 1

THE PATENTS ACT, 1970  
(39 of 1970)

APPLICATION FOR GRANT OF PATENT  
[See sections 7 and 135]

We, Cipla Limited, a company incorporated under the Indian Companies Act, 1913, whose address is 289, Bellasis Road, Mumbai Central, Mumbai – 400 008, Maharashtra, India, do hereby declare :-

- (a). that we are in possession of an invention titled "AN IMPROVED MULTI DOSE INHALER"
- (b). that the Provisional Specification relating to this invention is filed with this application.
- (c). that there is no lawful ground of objection to the grant of a patent to us.

We further declare that the Inventors for the said invention are Amar Lulla an Indian National of 103, Makers Tower, L 10<sup>th</sup> Floor, Cuff Parade, Colaba, Mumbai – 400 005; Geena Malhotra an Indian National of 4, Anderson House, Opp. Mazgaon Post Office, Mazgaon, Mumbai – 400 010 and Xerxes Rao an Indian National of Flat No. 802, Moraba Mansion, Plot No. 405, Linking Road, Khar (W), Mumbai – 400 052.

That we are the assignee of the true and first Inventors.

That our address for service in India is as follows :

Krishna & Saurastri,  
74/F, Venus, Worli Sea Face,  
Mumbai – 400 018, India.

Following declaration was given by the Inventor or Applicant in the convention country:

We are the true and first inventors for this invention or the Applicant in the convention country declare that the Applicant herein is our assignee.

- a). Amar Lulla an Indian National of 103, Makers Tower, L 10<sup>th</sup> Floor, Cuff Parade, Colaba, Mumbai – 400 005, Maharashtra, India.
- b). Geena Malhotra an Indian National of 4, Anderson House, Opp. Mazgaon Post Office, Mazgaon, Mumbai – 400 010, Maharashtra, India.
- c). Xerxes Rao an Indian National of Flat No. 802, Moraba Mansion, Plot No. 405, Linking Road, Khar (W), Mumbai – 400 052, Maharashtra, India.



(AMAR LULLA)



(GEENA MALHOTRA)



(XERXES RAO)

P.T.O.

duplicate  
7001 MUM 103

That to the best of our knowledge, information and belief the fact and matters stated herein are correct and that there is no lawful ground of objection to the grant of patent to us on this application.

Following are the attachment with the application :

- (a). Form 1 (duplicate)
- (b). Form 3 ( - do - )
- (c). Form 5 ( - do - )
- (d). Provisional Specification & Drawings (duplicate)
- (e) Photocopy of the General Power of Attorney.
- (f) Fees of Rs. 3,000/-

We request that a patent may be granted to us for the said invention.

Dated this 9th day of July, 2003.

FOR CIPLA LIMITED



Signature :  
Name : Amar Lulla  
Designation : Director

To,  
The Controller of Patents  
The Patent Office  
Mumbai.

THE PATENTS ACT, 1970  
(39 of 1970)

PROVISIONAL SPECIFICATION  
[See section 10]

AN IMPROVED MULTIDOSE INHALER;

CIPLA LIMITED, A COMPANY  
INCORPORATED UNDER THE INDIAN  
COMPANIES ACT, 1913, WHOSE  
ADDRESS IS 289 BELLASIS ROAD,  
MUMBAI CENTRAL, MUMBAI - 400 008,  
MAHARASHTRA, INDIA;

THE FOLLOWING SPECIFICATION  
DESCRIBES THE NATURE OF THIS  
INVENTION.

original  
700/MUM/03  
917103

TITLE:

AN IMPROVED MULTIDOSE INHALER

FIELD OF INVENTION:

The present invention relates to the field of inhalers. Particularly, the present invention relates to the field of multidose inhalers especially those comprising a pierceable sealed cartridge having a plurality of medicament cavities, for administration of predetermined dosage of powder medicament to a patient by inhalation.

PRIOR ART:

Conventionally, a wide variety of multidose inhalers are available in the market, which are designed for convenient handling and inhalation of predetermined dosage of medicament by a patient.

Reference is hereby made to applicant's co-pending application No 975/MUM/2002 dated November 12, 2002 (provisional patent specification) which discloses an inhaler having top and bottom containers enclosing a circular cartridge of medicament comprising a plurality of cavities holding a predetermined quantity of medicament. A spike member, operable by the user, is pressed down by hand, to pierce the foil sealing the cartridge and thereby begin inhalation of the medicament through a mouth piece. However, once the inhalation from one cavity is completed, then fresh medicament cavity is brought to inhalation position by manually lifting the spike fully or to a certain height above the top container, and then rotating the top container relative to the bottom container.

However, in the above type of inhalers, the user has to perform multiple operations for inhaling a specified dosage of medicament.

The present invention provides an improved multidose inhaler which overcomes and finds solution to problems associated with the above inhaler and various other inhalers known in the art.

The multidose inhaler according to the present invention, comprises very less number of moving parts, provides extreme ease of use, and offers very high level of performance.

#### BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 shows the exploded sectional view of the components of the inhaler according to the present invention.

Fig. 2 shows the plan, sectional elevation and side views of the top cap according to the present invention

Fig. 3A shows the plan and sectional elevation of the base cap according to the present invention.

Fig. 3B shows the plan, front and side sectional views of the center cap according to the present invention.

Fig. 4 shows the top and sectional front view of the spike according to the present invention

Fig. 5 shows the plan and sectional view of the medicament cartridge according to the present invention.

Fig. 6A shows the top and sectional elevation of the lever according to the present invention.

Fig.6B shows the plan and sectional elevation of the spiral torsion spring according to the present invention.

Fig. 6C shows the plan and sectional elevation of the drum according to the present invention.

Fig. 7A shows the plan, sectional elevation and side views of the mouth piece according to the present invention.

Fig. 7B shows the plan and elevation of the pin according to the present invention.

Fig. 7C shows the plan and elevation of the spring which energizes pin of Fig. 7B according to the present invention.

#### DESCRIPTION:

The present invention discloses a multidose inhaler (hereinafter referred to as a device), the constructional and functional features of which will become apparent from the description given herein:

FIG 1 : The multidose inhaler according to the present invention comprises a base cap (1) and a top cap (2), with a centre cap (3) located between the base cap (1) and the top cap (2) and all of said caps lockably assembled in a manner as shown in Fig.1.

The base cap (See Fig 3A) comprises a substantially circular body (1a) having a central sleeve member (1b) and a slit (1c) located substantially in close proximity to the sleeve member (1b). Other features and functions of the base cap (1) which would enable assembly of the device, would be apparent from the drawings accompanying this specification.

Fig 2 : shows the plan, elevation and side views of the top cap (2). In the embodiment shown, the top cap (2) comprises a substantially circular body, having a projection (2a) at a substantially central location of the body. The projection (2a) engages with the sleeve member (1b) of the base cap (1) for lockably assembling the top cap (2) in snap - fitting relationship with the base cap (1). In the locked state, only the relative rotation of the top cap (2) against the base cap (1) is enabled.

A dust cap (2b) is configured at the circumferential edge the top cap (2). A set of cam members (2c) are configured on the under side surface of the top cap (2). The cam members (2c) are preferably arranged in pair, in opposite sides as shown in FIG 2b. The cam members (2c) are preferably gradually tapering profiles projecting from the underside surface of the top cap (2). Alternatively, various profiles and features which would function substantially in a similar way to achieve substantially similar result are deemed to be within the scope of this invention.

Fig 3 B: shows the plan, elevation and sectional view of the centre cap (3). The centre cap (3) comprises a substantially circular body having a passage (3a) for guiding the flow of powder medicament. A lever (4) (shown in detail in Fig 6A) is pivotally mounted at a fulcrum point (4b) which is located substantially at the central portion of the centre cap (3). A mouth piece (5) (shown in Fig 7A) is mounted onto the passage for guiding the flow of powder medicament and facilitating inhalation by user. The dust cap (2b) openably closes the mouth piece (5) when the top cap (2) is relatively rotated against the base cap (1). At one position of the top cap (2) in assembled state with the centre cap (3) and the base cap (1), the dust cap (2b) closes the mouth piece (5) and in other relatively



rotated position against the base cap (1), opens the mouth piece (5) for inhalation of medicament by the patient.

Fig 5: shows the plan and elevation of the medicament cartridge (6). The medicament cartridge (6) comprises a plurality of cavities (6a) for holding a predetermined quantity of medicament thereto for inhalation by user. A thin pierceable foil (not shown) is normally used for sealing the cavities (6a) of the medicament cartridge (6). Several radial projections (6b) which impart rigidity and which assist in indexing movement of the cartridge (6) are integrally molded along with the cartridge (6).

Fig 4: shows the plan and elevation of a spike (7). The spike (7) comprises a hollow cylindrical body having an axial flow path (7a) and a venturi flow path (7b). The venturi flow path (7b) is oriented substantially perpendicular to the axial flow path (7a). The venturi flow path (7b) has at least one converging path (7d) and at least one diverging path (7c) with a substantially narrow constriction of substantially uniform cross section in-between the converging and diverging flow paths.

The purpose of the venturi flow path (7b) is to reduce the resistance to flow of powder medicament from the medicament cavity towards the mouth piece (5) upon inhalation by the user.

The spike has a head (7f) which is in contact with the lever (4) for enabling upward and downward movement of the spike (7) by the lever (4).

During assembly of the device, the medicament cartridge (6) is positioned within the base cap (1), in concentric relationship with the sleeve member (1b) of the base cap (1).

A spiral torsion spring (8) (shown in Fig 6B) hereinafter referred to as torsion spring, is mounted at the periphery of the sleeve member (1b) in-between the medicament cartridge (6) and the sleeve member (1b). The inner end (8b) of the torsion spring (8) is fixed onto the slit (1c) adjoining the sleeve member (1b). A drum (9) (as shown in Fig 6C) is mounted over the base cap (1), enclosing the torsion spring (8). The outer end (8a) of the torsion spring (8) is fixed to the drum (9) in a substantially energized condition such that the torsion spring (8) tends to unwind thereby rotating the drum (9) by virtue of the kinetic energy released during unwinding of the torsion spring (8).

The drum (9) has slit (9a) which is matched with a projection (6c) of the medicament cartridge (6) as shown in Fig 5 such that the medicament cartridge (6) and the drum (9) are in fixed relationship with each other. As the torsion spring (8) is unwound, the drum (9) rotates thereby rotating the medicament cartridge (6) along with the drum (9).

The fitting of the medicament cartridge (6) and the drum (9) may be achieved by suitable mechanism known in the art for achieving the purpose.

At least a pair of spring loaded pins (10) (see Fig 7B & 7C) are mounted below the top cap (2), in coordination with the radial projections (6b) of the medicament cartridge (6) for enabling indexing movement of the medicament cartridge (6).

The top cap (2) is configured such that when the top cap (2) is rotated relative to the base cap (1), say for about 60 degrees, the opening of the mouth piece (5) by

the dust cap (2b), indexed movement of the medicament cartridge (6) and the piercing of the foil for fresh medicament inhalation are simultaneously effected.

The indexing movement of the medicament cartridge, according to the present invention refers to the preset degree of unidirectional rotation of the medicament cartridge, for corresponding relative rotation of the top cap (2) against the base cap (1).

This indexing movement is achieved by the following configuration of the top cap (2) and the associated components thereof described herein:

At predetermined relatively rotated positions of the top cap (2) with the base cap (1), at least one among the pair of spring loaded pins (10) is set in energized downward position by at least one of the cam members (2c) such that the downwardly energized pin (10) obstructs and stops the rotation of the medicament cartridge (6) which otherwise rotates by virtue of the kinetic energy of the torsion spring (8). Preferably, for a 0 – 60 degree relative rotation of the top cap (2) with the base cap (1), the degree of rotation of the medicament cartridge (6) is set such that an exhausted cavity is replaced by a fresh medicament cavity for inhalation by the patient.

It is to be noted that the torsion spring (8) in substantially energized condition, is used for imparting continuous rotation to the medicament cartridge (6). The spring mentioned in relation to the spring loaded pin is preferably, a conventional helical spring ( as shown in Fig 7C).

Furthermore, at least one of the cam members (2c) is in substantial contact with the lever (4).

As the top cap (2) rotates, the cam members (2c) effect corresponding downward or upward movement of the lever (4) so as to respectively lift or push the spike (7) for effecting piercing of the foil by the spike (7).

In normal closed position of the top cap (2), atleast one pin (10) contacts the radial projection (6b) of the cartridge (6) thereby holding the cartridge in stationary position against the rotational force exerted due to kinetic energy the torsion spring.

As the top cap (2) is rotated relative to the base cap (1), atleast one of the cam members (2c) effect movement of atleast one pin (10) towards upward position, thereby releasing the contact of the pin (10) with the radial projections (6b) and subsequently allowing predetermined degree of rotational movement of the cartridge (6).

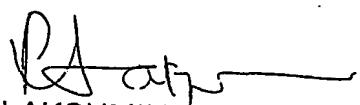
In one embodiment, atleast a pair of such pins (10) coordinate with atleast a pair of cam members (2c) to effect two stage rotational movement of the cartridge (6) from one cavity position to another thereby bringing fresh medicament cavity to inhalation position for inhalation of medicament by the patient.

The medicament cartridge used herein is loaded at the time of assembly and once the cartridge is exhausted, further rotation of the cartridge is stopped.

Further details of the invention will be apparent from the drawings accompanying this specification.

Dated this 9<sup>th</sup> day of July, 2003.

FOR CIPLA LIMITED  
By their Agent

  
(R. LAKSHMINARAYANAN)  
KRISHNA & SAURASTRI

Name : Cipla Limited

Sheet No. : 1

Appl.No. : /MUM/2003

Total Sheets : 6

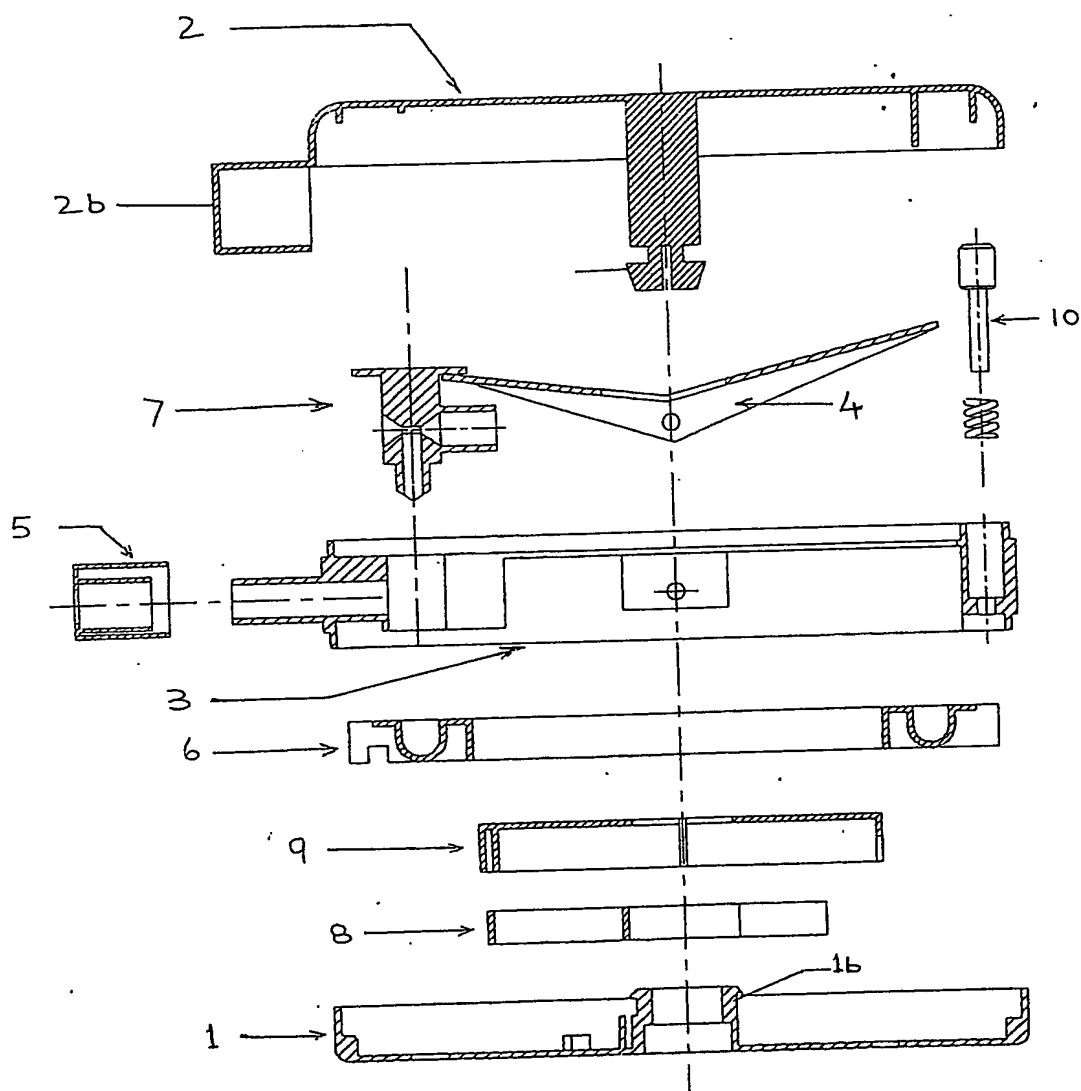


FIG-1

  
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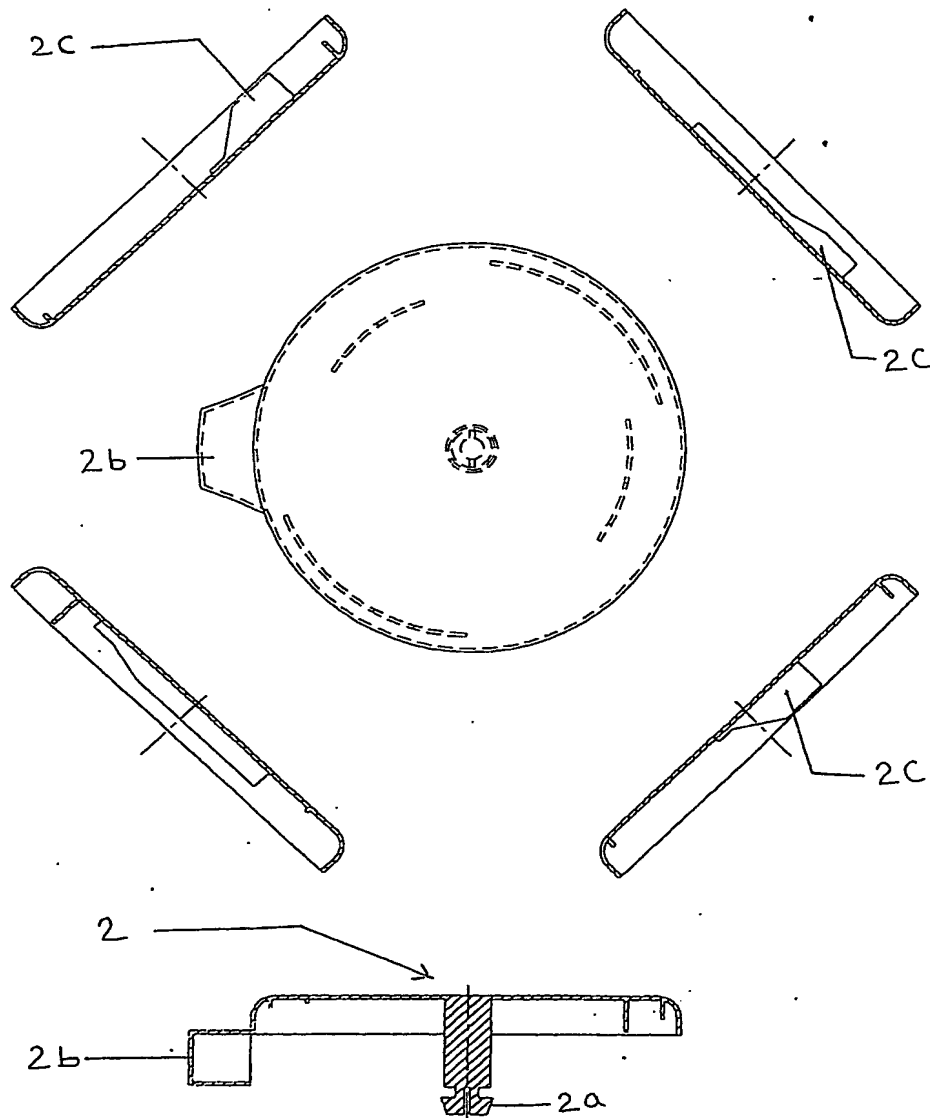



FIG - 2

  
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FIG-3A

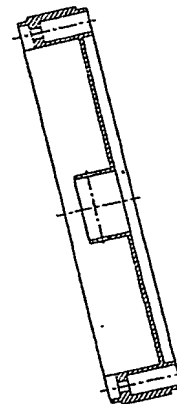
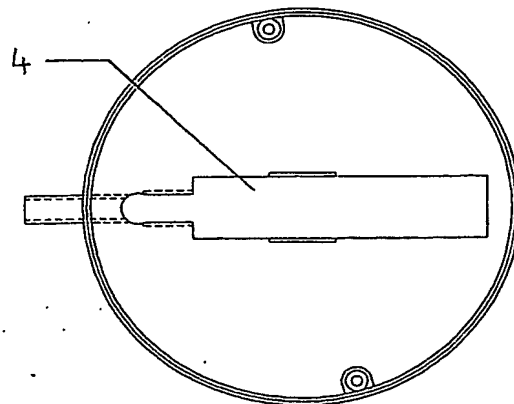
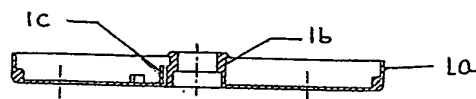
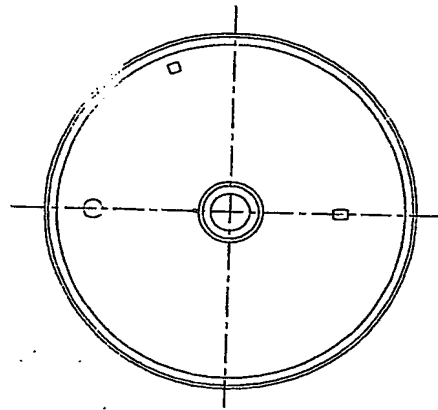



FIG-3B

  
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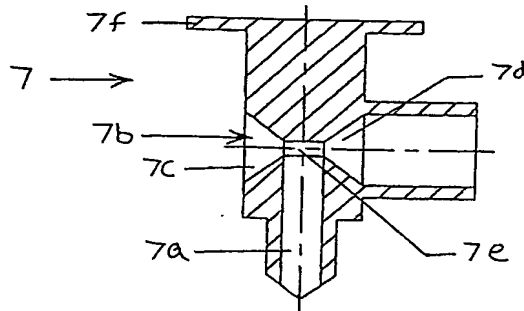
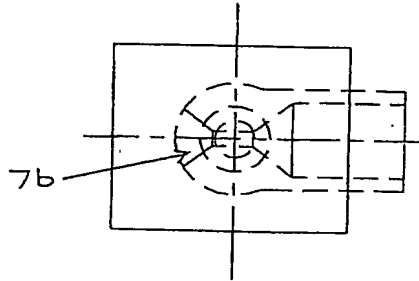


FIG-4

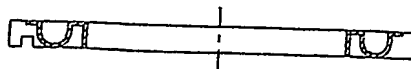
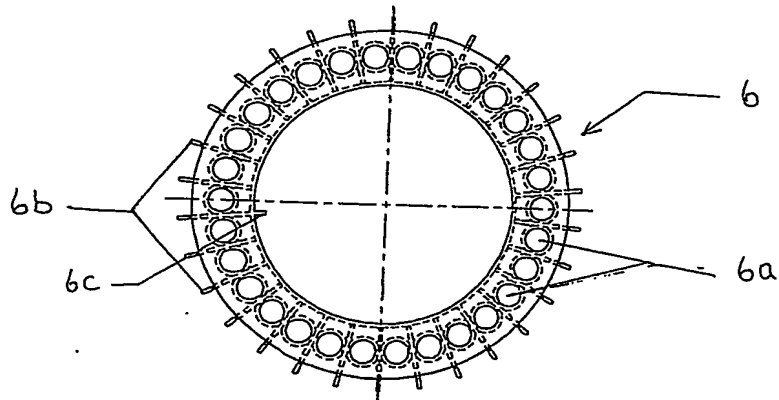



FIG-5

  
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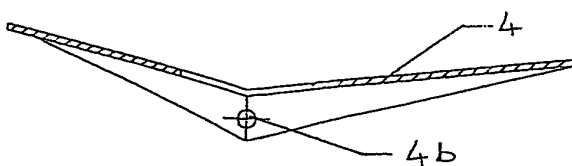
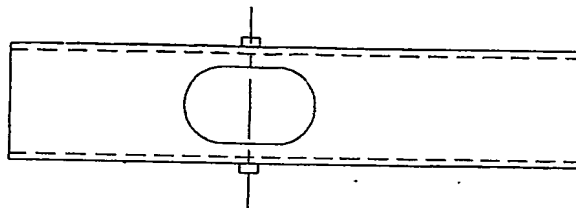


FIG-6A

FIG-6B

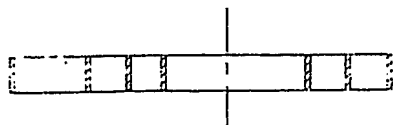
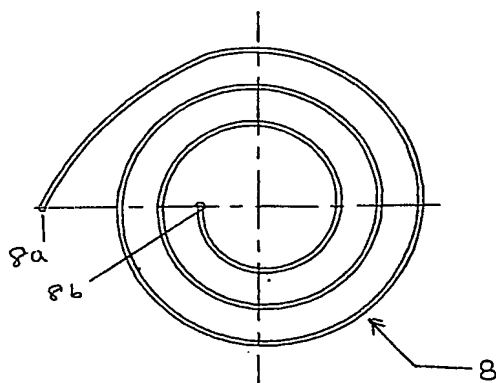
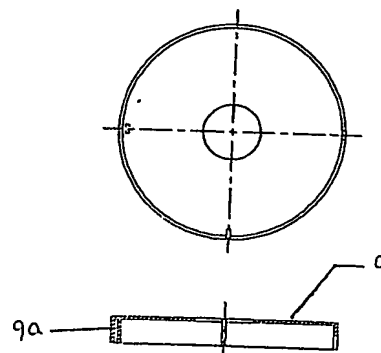


FIG-6C



(R. LAKSHMINARAYANAN)  
KRISHNA & SAURASTRI

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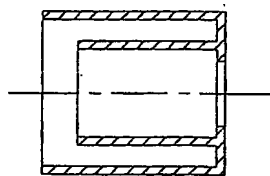


FIG-7A

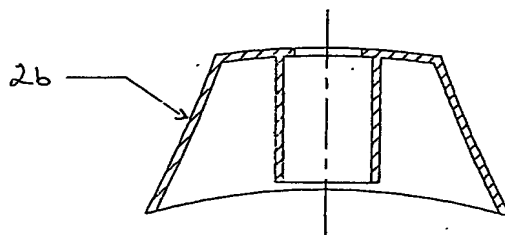
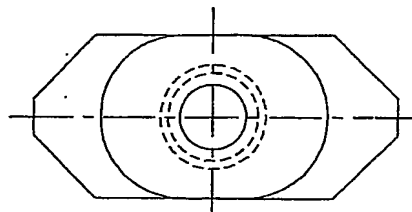


FIG-7B

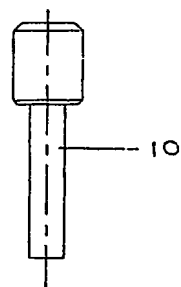
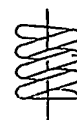


FIG-7C



(R. LAKSHMINARAYANAN)  
KRISHNA & SAURASTRI

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